

Claims

1. An oral dosage form comprising a core material coated with a semipermeable membrane wherein the core material comprises an active ingredient selected from the group of omeprazole, an alkaline salt thereof, *S*-omeprazole and an alkaline salt thereof, in admixture with one or more alkaline additives, one or more swelling agents, and optionally pharmaceutically acceptable excipients, and the dosage form is not enteric coated
2. A dosage form according to claim 1 wherein the semipermeable membrane is able to disrupt.
3. A dosage form according to claim 1 wherein the active ingredient is omeprazole.
4. A dosage form according to claim 1 wherein the active ingredient is a magnesium salt of omeprazole having a crystallinity of more than 70% determined by X-ray powder diffraction.
5. A dosage form according to claim 1 wherein the active ingredient is magnesium salt of *S*-omeprazole.
6. A dosage form according to claim 1 wherein the core material comprises a sugar sphere layered with a suspension or solution of the active ingredient, one or more alkaline additives, one or more swelling agents and optionally pharmaceutically acceptable excipients.
7. A dosage form according to claim 1 wherein the dosage form comprises individual pellets of the core material coated with the semipermeable membrane.
8. A dosage form according to claim 1 wherein the core material comprises a further component in the form of an osmotic agent.

9. A dosage form according to claim 1 wherein the alkaline additive is an agent selected from the group of compounds that give a pH of not less than 8.5 when measured in a 2% w/w water solution/dispersion with a pH-measuring electrode.

5 10. A dosage form according to claim 9 wherein the alkaline additive is an agent selected from the group of disodium hydrogen phosphite, trisodium phosphate, arginine and talc.

11. A dosage form according to claim 1 wherein the alkaline additive is present in an amount of approximately 5 to 35 % by weight of the core material excluding the weight of
10 an optional sugar sphere.

12. A dosage form according to claim 1 wherein the alkaline additive is present in an amount of 15 to 35 % by weight of the core material excluding the weight of an optional sugar sphere.

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13. A dosage form according to claim 1 wherein the swelling agent is selected from the group of crosslinked polyvinyl pyrrolidone, crosslinked sodium carboxymethylcellulose, sodium starch glycolate and low-substituted hydroxypropyl cellulose (L-HPC).

20 14. A dosage form according to claim 1 wherein the swelling agent is present in an amount of approximately 20 to 60 % by weight of the core material excluding the weight of an optional sugar sphere.

15. A dosage form according to claim 1 wherein the swelling agent is present in an
25 amount of 30 to 50 % by weight of the core material excluding the weight of an optional sugar sphere.

16. A dosage form according to claim 1 wherein the semipermeable membrane comprises a water insoluble polymer and a modifying agent such as talc or fumed silica.

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17. A dosage form according to claim 1 wherein the water insoluble polymer is selected from the group of ethylcellulose, cellulose acetate, polyvinyl acetate, and ammonio methacrylate copolymer type A and type B.

5 18. A dosage form according to claim 1 wherein the water insoluble polymer is present in an amount of approximately 3-30% by weight of the core material.

19. A dosage form according to claim 1 wherein the semipermeable membrane comprises a modifying agent and a water insoluble polymer in a ratio of between 90:10 and 50:50.

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20. A process for the manufacture of a dosage form as defined in claim 1, wherein a core material is formed comprises an active ingredient selected from the group of omeprazole, an alkaline salt thereof, *S*-omeprazole and an alkaline salt thereof, in admixture with one or more alkaline additives, one or more swelling agents, and optionally pharmaceutically
15 acceptable excipients, the core material is coated with a semipermeable membrane and has no enteric coating.

21. Use of an oral pharmaceutical dosage form as defined in any of claims 1 - 19 in the manufacture of a medicament with improved inhibition of gastric acid secretion.

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22. Use of an oral pharmaceutical dosage form as defined in any of claims 1 - 19 in the manufacture of a medicament with improved therapeutic effect in the treatment of gastrointestinal disorders associated with excess acid secretion.

25 23. A method for improving inhibition of gastric acid secretion which comprises administering to a patient in need thereof, an oral pharmaceutical dosage form as defined in any of claims 1 - 19.

24. A method for improving the therapeutic effect in the treatment of gastrointestinal
30 disorders associated with excess acid secretion which comprises administering to a patient in need thereof, an oral pharmaceutical dosage form as defined in any of claims 1 - 19.